ONE HUNDRED ELEVENTH CONGRESS

## Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE 2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

> Majority (202) 225–2927 Minority (202) 225–3641

December 1, 2009

The Honorable Barack Obama President The White House 1600 Pennsylvania Avenue, N.W. Washington, D.C. 20500

## Dear Mr. President:

I am writing to draw your attention to a critical public health matter which was dangerously neglected by the Bush Administration, and ask that you remedy these years of inaction. In a subversion of the intent of the Congress, the Bush White House chose to deny communities free access to a potentially life-saving drug, potassium iodide (KI). KI is a safe, stable, and inexpensive compound that has been approved by the Food and Drug Administration for the protection of the public, particularly children and pregnant women, against radiation-induced cancers in the event of a nuclear emergency. One need only look at cancer rates after the Chernobyl disaster: those who had taken KI were far less likely to develop radiation-induced cancers.

In 2002, I authored Section 127 of the Bioterrorism Preparedness and Response Act, which directed the President to establish a program to make KI available to State and local governments for distribution to residents living within 20 miles of a nuclear power plant. Previously, distribution was limited to just those within 10 miles, and only at the States' initiatives. The 2002 Act also required the National Academy of Sciences (NAS) to produce a comprehensive scientific study of KI's efficacy, safety and distribution. This study, completed in 2004, recommended that:

<sup>&</sup>lt;sup>1</sup> Nauman J, Wolff J. (1993) Iodide prophylaxis in Poland after the Chernobyl reactor accident: Benefits and risks. *The American Journal of Medicine*, Volume 94, Issue 5, Pages 524-532.

- "KI should be available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident"; and
- "KI distribution should be included in the planning for comprehensive radiological incident response programs for nuclear power plants. KI distribution programs should consider predistribution, local stockpiling outside the emergency planning zones (EPZ), and national stockpile and distribution capacity."

The Congress' choice of a 20-mile KI distribution radius was driven by its recognition that radiological exposure during a nuclear emergency is almost certain to exceed the "intervention level", set by the Nuclear Regulatory Commission (NRC) to 5 rem, at distances greater than 10 miles from the event. Two NRC-commissioned technical studies predicted exposure at 25 miles from the event to be over 1000 rem, with the probability of thyroid damage to an adult outdoors to be 40%. For infants and children, the potential for damage is much higher.<sup>2</sup>

Despite the unequivocal Congressional mandate, a favorable report from the NAS,<sup>3</sup> and the NRC's own studies, the Bush Administration delayed and obfuscated for years.

Following the 2004 NAS report, draft guidelines from the Department of Health and Human Services (HHS) were published in August 2005 – two years overdue. My letter to President Bush in February 2006 expressed concern that the final HHS regulations were being held up due to spurious arguments raised by the NRC and the nuclear utility industry. In response, I received a letter in August 2006 from then-HHS Secretary Leavitt who wrote, "We are not aware of any 'alternative and more effective prophylaxis or preventive measures' that could be offered in place of potassium iodide in conjunction with other protective measures, and the President has not invoked subsection (f) of the Act. HHS has therefore proceeded with finalizing the KI distribution guidelines."

Despite those assurances from HHS, as well as a letter from me, then-House Energy and Commerce Committee Chairman Dingell, Health Subcommittee Chairman Pallone and Oversight and Investigations Subcommittee Chairman Stupak that went unanswered, President Bush chose to subvert the intent of the Congress, the views of his own HHS Secretary, and the recommendations of the NAS. His administration invoked Section 127(f) of the Act, which Congress had included to allow halting of KI distribution only if superior radiation protection was achieved in the future with a newly-developed drug or method. However, instead of citing a new prophylaxis, the Bush Administration declared

<sup>&</sup>lt;sup>2</sup> NUREG/CR-1433, Sandia National Laboratories, October 1980, and NUREG/CR-6310, S. Cohen & Associates, April 1992.

<sup>&</sup>lt;sup>3</sup> Similar positions are held by the World Health Organization, the American Academy of Pediatrics, the American Thyroid Association, the National Council on Radiation Protection, and the FDA, as well as the governments of Germany, Sweden and the United Kingdom.

<sup>&</sup>lt;sup>4</sup> Sent 11/9/07 to OMB Director Nussle from Chairman Dingell and subcommittee chairs Markey, Stupak, and Pallone. http://energycommerce.house.gov/Press\_110/110-ltr.110907.OMB.Iodide.pdf

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that evacuation and removal of contaminated foodstuffs were "more effective... preventative measures [than KI] for adverse thyroid conditions that may result from the release of radioiodide from nuclear power plants."

Evacuation and removal of exposed food and water would certainly prove to be woefully inadequate or ineffectual in the face of a major nuclear emergency. We need only remember the tragic events following Hurricanes Katrina and Rita – events for which we had advanced warning. Even with notice, the local and state governments were unable to evacuate effectively, or provide adequate food and water to those who remained behind. During a radiological incident, evacuation will likely be a useful tool. However, given the difficulty of evacuation and the likely necessity of sheltering-in-place, it is even more baffling that KI would be kept from those in the 11-20 mile radius – particularly as they could be expected to remain behind while those in the 10-mile EPZ are evacuated.

Similarly, contaminated food removal is impractical and only marginally effective. Not only would it require the replacement of contaminated food with uncontaminated food over several thousand square miles in the midst of a major crisis, but the focus on food fails to recognize that inhalation, not ingestion, is the primary mode of radioiodine exposure. According to the NRC's own research, exposure is "dominated by inhalation of radioiodine" and that "protective measure[s] must reduce the inhalation dose." 5

Potassium iodide is a safe, convenient and highly effective way to safeguard public health against a radiological event. Not only is the science sound, but the financial mechanism to stockpile KI is already in place with the Project BioShield Act of 2004, which funds countermeasures against biological, chemical, radiological and nuclear agents (\$5.6 billion through FY2013).<sup>6</sup> A six-day course of KI, with a 10-year shelf life, costs \$1.80. That brings the cost of protection to just 18¢ per year per person.

It is all too easy to imagine an accident like Three Mile Island or a terrorist attack targeting our nation's nuclear infrastructure. In the event of a radiological emergency, the immediate use of KI within the affected area would constitute a crucial aspect of a successful emergency response.

In 2002 the Congress required the President to make KI available to those living nearest to our 104 currently operating nuclear power plants. The exercise of this power is now long overdue, leaving many Americans living near these plants needlessly at risk. I urge you to fully implement the Bioterrorism Preparedness and Response Act by revoking the declaration improperly made by your predecessor, in contravention of the clear intent of the law, and by directing the NRC or HHS to make KI available to those within 20 miles of a plant. I also ask that you immediately order HHS to renew its KI stockpile, which is currently set to expire in 2012.

<sup>&</sup>lt;sup>5</sup> NUREG/CR-1433, Sandia National Laboratories, October 1980.

<sup>&</sup>lt;sup>6</sup> The FY2004 DHS Appropriations Act (PL 108-90) and the FY2004 Emergency Supplemental Appropriations Act (PL 108-106)

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Thank you for your consideration of this request. If you have any questions or concerns, please contact me, or have your staff contact Dr. Katie Matthews of my staff at (202) 225-2836. I look forward to your response.

Sincerely,

Edward J. Marke

Chairman

Subcommittee on Energy and Environment